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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,090	02/14/2002	Susana Salceda	DEX-0312	5706
26259	7590	10/26/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			BORIN, MICHAEL L	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,090

Applicant(s)

SALCEDA ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Status of Claims

1. Response filed 08/19/2004 is acknowledged. Claims 6,10-17 are canceled. Claims 18-21 are added. Claims 1-5,7-9,18-21 are pending.

In response to include polynucleotide SEQ ID No. 47, Examiner agrees that there is some overlap in the sequences of two polynucleotides of SEQ ID No. 47 and 48, but maintains that neither specification nor claims identify common core structure necessary for a common utility. The restriction requirements was made final in the previous Office action.

Claim 18 is withdrawn from consideration as drawn to non-elected subject matter.

Claims 1-5,7-9,19-21 are under consideration to the extent they read on the elected subject matter.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections and/or objections are either reiterated and constitute the complete set presently being applied to the instant application.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is denied. Applicant demonstrated description of SEQ ID No. 47 in provisional application. However, SEQ ID No. 48, which is the elected subject matter, is not disclosed in the priority application. Partial overlap of a shorter SEQ ID No 47 and much longer

SEQ ID No. 48 is recognized; however, it is not sufficient to demonstrate that applicant was in possession of polynucleotide SEQ ID No. 48 at the time of filing of the provisional application. Consequently, the claims, as directed to SEQ ID No. 48, are granted priority only to the filing date of instant application.

Claim Objections

3. Claims 1-5, 7-9, 19-21 are objected because they do not reflect the elected subject matter. Applicant elected polynucleotide SEQ ID No. 48 encoding polypeptide SEQ ID No. 151. The claims do not reflect the elected subject matter as they read on SEQ ID No. 47 as well. Amendment of the claims to read on the polynucleotide of SEQ ID 48 is repeatedly requested.

Claim Rejections - 35 U.S.C. § 101/ 112-1

4. Claims 1-5, 7-9, 19-21 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that polynucleotide SEQ ID No. 48 is overexpressed in breast cancer tissues. The latter is presumably demonstrated in the Table – see p. 116, line 6. However, it seems that data of the Table are coming straight from the provisional application which does not disclose SEQ ID No. 48 of the instant

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application. See p. 29-33 of the provisional application 60/268999, p. 31, lines 24-27, in particular. Note that the length of the clone comprising, presumably, SEQ ID No. 48, is much shorter (555 bases) than SEQ ID No. 48 itself (1667 bases); also SEQ ID No. 48 described in the provisional application is different from instantly claimed SEQ ID No. 48. Applicant is invited to provide further proof that polynucleotide SEQ ID No. 48 of the instant application is indeed overexpressed in breast cancer tissue.

If polynucleotide SEQ ID No. 48 had been demonstrated to be overexpressed in breast cancer tissues, the utility rejection will be changed to scope of enablement rejection in regard to other nucleic acid molecules encoding amino acid sequence of SEQ ID No. 151.

5. Claims 1-5, 7-9, 19-21 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a substantial or a well-established utility for the reasons set forth above, one skilled in the art would not know how to make and/or use the claimed invention.

6. Claims 1-5, 7-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that providing ATCC deposit number for clone containing SEQ ID No. 48 demonstrates applicant's possession of other elements included in

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DNA. First, as discussed above, length of clones comprising, presumably, SEQ ID No. 48, is much shorter than SEQ ID No. 48 itself. See p. 116, lines 5-8, which demonstrates four clones of various length from 555 to 885, as compared to 1677 bases in SEQ ID No. 48. Second, SEQ ID No. 48 described in the provisional application (Fig.48) is different from instantly claimed SEQ ID No. 48 and the clone containing it does not describe the clone containing SEQ ID No. 48 of the instant application. Therefore the clones do not contain full SEQ ID No. 48, much less any additional elements addressed in the rejection.

Claim Rejections - 35 USC § 102

7. Claims 1-5 remain rejected under 35 U.S.C. 102(a) as being anticipated by the sequence of Accession number BF953475 (01/2001), Database EST or Accession number AL110228, Database GenEmbl. The referenced sequences show more than 95% similarity to regions of SEQ ID No. 48 of the instant invention (see attached sequence alignment). As the referenced sequences have continuous stretches matching the claimed sequence of SEQ ID No. 48 (see attached sequence alignment) it would be expected to selectively hybridize to SEQ ID No. 48, absent evidence to the contrary.

The claims are amended to specify hybridization conditions (claim 1(c)). Calculation of melting temperatures for hybridizing the referenced sequences under the conditions now claimed yields melting temperatures of 70.08°C and 70.53°C, respectively; therefore the referenced sequences will hybridize under the claimed conditions.

The rejection is maintained.

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8. Claims 1-5 remain rejected under 35 U.S.C. 102(a) as being anticipated by Accession number AB040959, Database Genemb (Nagase et al., DNA Research, 7, 143-150, 2000); see attached sequence alignment. The referenced sequences have 96% similarity to polynucleotide encoding polypeptide SEQ ID No. 151.

The claims are amended to specify hybridization conditions (claim 1(c)). Calculation of melting temperatures for hybridizing the referenced sequences under the conditions now claimed yields melting temperatures of 70.73°C ; therefore the referenced sequences will hybridize under the claimed conditions.

The rejection is maintained.

Conclusion.

8. No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

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